

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF  
DIETMAR HÜGLIN ET AL  
CONT OF APPLICATION NO: 09/306,005  
FILED: CONCURRENTLY HERewith  
FOR: USE OF NANODISPERSIONS IN  
COSMETIC END FORMULATIONS

Group Art Unit: 1615  
Examiner: G. Kishore

Assistant Commissioner for Patents  
Washington, D.C. 20231

**PRELIMINARY AMENDMENT**

Sir:

Kindly amend this application as follows prior to calculation of the filing fee and consideration on the merits.

**IN THE CLAIMS**

Please cancel without prejudice claims 1-31.

Please add the following claims.

--32. (new) A method of preparing a cosmetic formulation of a lipophilic cosmetic active agent in the form of an aqueous nanodispersion, which steps consist essentially of

(α) mixing the components

(a) 0.1 to 30 % by weight of a phospholipid,

(b) 1 to 50 % by weight of a polyoxyethylene coemulsifier,

(c) 0.1 to 80 % by weight of a lipophilic component which is a natural or synthetic or a partially synthetic C<sub>4</sub>-C<sub>18</sub> triglyceride and a lipophilic cosmetically active agent, in which any cosmetically active agent is lipophilic and is always present in component (c), and

(d) 7.40 to 14.2 % by weight of ethanol,

with conventional stirring apparatus until a homogeneous clear liquid is obtained, and

(β) adding the liquid obtained in step (α) to a water phase, wherein step (β) is carried out in the absence of high shear or cavitation forces, and wherein the particles in the nanodispersion have an average diameter of <50 nm.

33. (new) A method according to claim 32, wherein step (α) is carried out in an anhydrous medium.

34. (new) A method according to claim 32, wherein component (b) in the nanodispersion is polyethoxylated sorbitan fatty acid esters, polyethoxylated fatty alcohols, polyethoxylated fatty acids, polyethoxylated vitamin E derivatives, polyethoxylated lanolin and derivatives thereof, polyethoxylated fatty acid partial glycerides, polyethoxylated alkylphenols, polyethoxylated fatty alcohols and salts thereof, polyethoxylated fatty amines and fatty acid amides, polyethoxylated carbohydrates or block polymers of ethylene oxide and propylene oxide.

35. (new) A method according to claim 32, wherein the nanodispersion comprises as component (c) a sunscreen or a fat-soluble vitamin.

36. (new) A method according to claim 32, wherein the nanodispersion is present in the cosmetic formulation in a concentration of 0.01 to 99 % by weight.

37. (new) A method of preparing a cosmetic formulation of a lipophilic cosmetic active agent in the form of an aqueous nanodispersion, wherein the cosmetic formulation is in the form of a gel which comprises a nanodispersion as defined in claim 32.

38. (new) A method of preparing a cosmetic formulation of a lipophilic cosmetic active agent in the form of an aqueous nanodispersion, wherein the cosmetic formulation is in the form of a cream, lotion or milk which comprises a nanodispersion as defined in claim 32.

39. (new) A method of preparing a cosmetic formulation of a lipophilic cosmetic active agent in the form of an aqueous nanodispersion, wherein the cosmetic formulation is in the form of a stick which comprises a nanodispersion as defined in claim 32.

40. (new) A method of preparing a cosmetic formulation of a lipophilic cosmetic active agent in the form of an aqueous nanodispersion, wherein the cosmetic formulation is in the form of a spray or aerosol which comprises a nanodispersion as defined in claim 32.

41. (new) A method of preparing a cosmetic formulation of a lipophilic cosmetic active agent in the form of an aqueous nanodispersion, wherein the cosmetic formulation is in the form of a foam which comprises a nanodispersion as defined in claim 32.

42. (new) A method of preparing a cosmetic formulation of a lipophilic cosmetic active agent in the form of an aqueous nanodispersion, wherein the cosmetic formulation is in the form of a paste which comprises a nanodispersion as defined in claim 32.

43. (new) A method of preparing a cosmetic formulation of a lipophilic cosmetic active agent in the form of an aqueous nanodispersion, wherein the cosmetic formulation is in the form of a powder, lacquer, pellet or cosmetic make-up which comprises a nanodispersion as defined in claim 32 in which the nanodispersion is present in dehydrated form.--

#### REMARKS

As pointed out in the parent application, applicants teach on page 2, third full paragraph:

Step ( $\alpha$ ) is usually carried out at room temperature, where necessary with heating and under normal pressure conditions. Mixing is carried out using standard [or conventional] stirring apparatus, for example propeller, angled paddle or magnetic agitators, and without using any special mechanical stirring aids.

Applicants further teach on page 2, last full paragraph:

Step ( $\beta$ ) is carried out by adding the liquid obtained in step ( $\alpha$ ), the nanodispersion prephase, to the water phase of the cosmetic end formulations. The particular choice of components (a), (b) and (c) results directly in ultrafine, monodisperse nanodispersions. In this case it is possible to forego homogenisation via nozzle, rotor-stator or ultrasound homogenisers, which is usually

carried out to convert coarsely disperse or at least heterodisperse systems to fine monodisperse systems. Step (β) is thus characterised by the absence of high shear or cavitation forces.

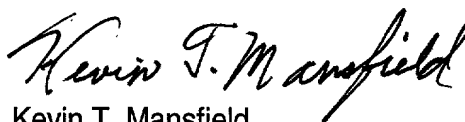
[Emphasis added]

Thus, applicants concede that the optional heating and/or conventional low shear stirring in step (α), provides some small amount of energy. Additionally, step (β) is carried out by adding the liquid obtained in step (α), the nanodispersion prephase, to a preheated water phase with conventional low shear stirring. See examples 7ff where a simple magnetic agitator is employed. Thus some thermal and some minimal amount of mechanical energy are also supplied in step (β). However applicants clearly teach that the high shear or cavitation forces employed in homogenisation via nozzle, rotor-stator or ultrasound homogenisers are not needed to obtain the inventive aqueous nanodispersions of cosmetic formulations.

Accordingly applicants have amended their claims in order to more particularly point out and distinctly claim their invention. Thus, claims 1-31 have been cancelled and replaced, in part, by newly added claims 32-45. Said claims 32-45 are the only claims pending. Said claims are supported by originally filed claims 1-31 and the disclosure as cited above. No new matter has been added.

Applicants aver that the claims are now in proper form for examination. An Action on the merits of the claims is respectfully awaited.

Respectfully submitted,



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